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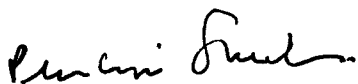
Thursday, April 16, 1998

Dr CW Jameson
National Toxicology Program
Report on Carcinogens
MD EC - 14
PO Box 12233 Research Triangle Park
NC 27709
USA

Dear Dr Jameson,

In response to your notice in the Federal Register of March 19th 1998, I enclose my comments on the recent hearing on the delisting of saccharin by the National Toxicology Program.

Sincerely yours,


Philippe Shubik DM DPhil

In the company of many others I was pleased to note that the National Toxicology Program (NTP) was to consider delisting saccharin from the list of compounds probably carcinogenic to the human. I am surprised that the action of the Board of Scientific Counselors did not follow through. There are many reasons for concluding that saccharin is probably safe for humans. The several chronic toxicity studies with saccharin in the rat revealed a compound that was unique in many respects. Very high doses are needed to induce a small number of tumors in one organ (the urinary bladder) only. The sex and age of the test rats are major determinants in the results. Above all the compound is not metabolized. There are, as far as I am aware, no established carcinogens exhibiting these characteristics. I believe that these findings permit a safe level for use in human to be set with confidence.

Unlike the majority of food additives it is fortunate that saccharin users can readily be identified in special populations allowing for good epidemiological studies . As a result many epidemiological studies have been performed and no adverse findings have occurred. Unfortunately many epidemiologists appear to be unable to conclude that any compound is completely safe. It defies common sense to conclude that the large number of competently performed studies with saccharin in the human do not demonstrate a lack of effect. It would be my view that the numerous studies with saccharin in the human should convince anyone that it is harmless.

The review by the National Toxicology Program (NTP) Board of Counselors contains numerous erroneous interpretations of data; at the top of the list is the acceptance of studies in mouse bladder, using implanted pellets, as valid evidence. Other studies in which saccharin is supposed to have induced thyroid tumors is, again, ill founded.

Overall this review does not seem to have the same degree of objectivity used in other NTP evaluations. I think that the NTP is missing an important opportunity to demonstrate their devotion to factual science in arriving at their important decisions.